

Art Unit: 1629

DETAILED ACTION

Claims 68, 71, 73-74 and 85-87 are presented for examination.

Applicant's Amendment filed March 14, 2011 has been received and entered into the present application.

Applicant's Information Disclosure Statement (IDS) filed April 14, 2011 (one page total) has been received and entered into the present application. As reflected by the attached, completed copy of form PTO/SB/08A, the Examiner has considered the cited references.

Claims 68, 71, 73-74 and 85-87 remain pending and under examination. Claims 68, 71, 85 and 87 are amended.

Applicant's Arguments, filed March 14, 2011, have been fully considered. Rejections and/or objections not reiterated from previous Office Actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set of rejections and/or objections presently being applied to the instant application.

Claim Rejections - 35 USC § 112, First Paragraph, Written Description Requirement

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 86 remains rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement because the claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention, for the reasons of record set forth at p.4-7 of the previous Office Action dated January 20, 2011, of which said reasons are herein incorporated by reference.

Art Unit: 1629

Response to Applicant's Arguments

Applicant traverses the instant rejection, stating that p.3 of the specification provides the chemical name of DMRIE and DORIE and urges that this provides adequate written descriptive support for these two compounds. Applicant opines that the compounds of claim 86 were synthesized as stated in the specification starting at p.52 *et seq.* and the specific functionalities are appended via the quaternary nitrogen as shown in Schemes III, IV and V. Applicant further refers to U.S. Patent No. 5,334,761 for relevant synthetic strategies, which is incorporated by reference. Applicant cites to Scheme III, Ex.1 for the synthesis of DMRIE carboxylate and Ex.1B for synthesis of DORIE carboxylate, as well as p.53 and Ex.3, 3A, 3B and 3C for the synthesis of the other compounds provided for in instant claim 86. Applicant also cites to U.S. Patent No. 6,670,332, which claims the same compounds as provided for in instant claim 86 and was not found to lack written description.

Applicant's traversal has been fully and carefully considered, but fails to be persuasive.

Firstly, Applicant urges that p.3 of the specification provides the chemical name of DMRIE and DORIE and urges that this provides adequate written descriptive support for these two compounds. This is unpersuasive in establishing adequate written description for the compounds provided for in instant claim 86 because it is not DMRIE or DORIE that are instantly claimed, but rather derivative compounds thereof, of which Applicant has failed to describe with sufficient specificity the actual chemical structures of these claimed DMRIE- or DORIE-based compounds. Though it is agreed that the chemical structure of DMRIE and DORIE is known and would have been understood by one of skill in the art, it is the chemical permutations thereof that are recited in instant claim 86 that are not adequately described in the instant specification so as to reasonably inform one of ordinary skill in the art at the time of the invention of the actual chemical structure and composition of these claimed compounds, i.e., dioleoyl rosenthal inhibitor ether carboxylate, dimyristyl rosenthal inhibitor ether carboxylate, DMRIE carboxylate propyl amide, DMRIE carboxylate methionine-methylester amide, DMRIE carboxylate methionine-leucine-

Art Unit: 1629

methylester amide and DMRIE carboxylate methionine-leucine-phenylalanine-methylester amide. As previously urged in the rejection, the lack of description of the actual chemical structures of these claimed compounds fails to set forth whether these anionic molecules fall within the generic structures presented in the specification and/or claims or if they are of a different, yet undescribed, chemical structure.

Secondly, Applicant opines that the compounds of claim 86 were synthesized as stated in the specification starting at p.52 *et seq.* and the specific functionalities are appended via the quaternary nitrogen as shown in Schemes III, IV and V. This is unpersuasive because the synthetic schemes describes in the instant specification p.52 *et seq.* are, at best, generic synthetic schema for providing "carboxy cytofectins", "carbamyl cytofectins" or "urea cytofectins", but do not provide any additional information to one of skill in the art as to the structures of the claimed cytofectins of instant claim 86. Indeed, while it is noted that Applicant has identified those cytofectins of instant claim 86 as "carboxy cytofectins" and while the relevant synthetic scheme identified as Scheme III is noted, this information still fails to adequately describe, without more, the actual physical chemical structure of these claimed cytofectins. The synthetic scheme amounts to no more than a generic synthetic plan using an undefined "carboxy" cytofectin without ever setting forth the identities of the various R-groups contained therein as would be contained in the compounds recited in instant claim 86. Thus, it is unclear how the skilled artisan could identify the relevance of such a scheme in providing a structural depiction of the claimed anionic molecules of instant claim 86 in the absence of any further information regarding the identities of these undefined R-groups in the starting and ending products. Note, also, for the record, that Scheme III provides four compounds (III-1, III-2, III-3 and III-4) but fails to set forth the distinction between the compound identified as III-2 and III-4, since each of III-2 and III-4 appears to have an identical chemical structure. Furthermore, Applicant's additional reference to U.S. Patent No. 5,334,761 as providing relevant synthetic strategies fails to remedy the deficiencies of the as-filed specification, because the '761

Art Unit: 1629

patent provides no more than generic synthetic schemes and does not provide adequate description of the chemical structure of the compounds recited in instant claim 86 that are presently under rejection.

Thirdly, Applicant cites to Scheme III, Ex.1 for the synthesis of DMRIE carboxylate and Ex.1B for synthesis of DORIE carboxylate, as well as p.53 and Ex.3, 3A, 3B and 3C for the synthesis of the other compounds provided for in instant claim 86. This is unpersuasive because these synthetic examples fail to provide any identifying information regarding the resultant end-product such that one of ordinary skill in the art at the time of the invention would have been reasonably apprised of the precise chemical identity of the compounds recited in instant claim 86. These synthetic descriptions fail to remedy the deficiency of the as-filed specification, namely that the as-filed specification lacks adequate description of the exact chemical structure of these anionic compounds. As such, the fact that such structures cannot be appropriately identified from the specification as filed fails to inform the skilled artisan of the identity of the compounds such that they could actually be used in accordance with the invention, which clearly fails to constitute a full written description of the invention as claimed.

Fourthly, and lastly, Applicant also cites to U.S. Patent No. 6,670,332, which claims the same compounds as provided for in instant claim 86 and was not found to lack written description. This is unpersuasive. Applicant is reminded that each case before the Office is decided on its own merits. Decisions made during the course of prosecution of previous applications are not binding to the course of prosecution of any other application pending before the Patent Office.

For these reasons *supra*, and those previously made of record at p.4-7 of the Office Action dated January 20, 2011, rejection of claim 86 is proper.

Claim Rejections - 35 USC § 112, Second Paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Art Unit: 1629

Claims 68 and 85 remain rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention, for the reasons set forth at p.8-9 of the previous Office Action dated January 29, 2011, of which said reasons are herein incorporated by reference.

Response to Applicant's Arguments

Applicant traverses the instant rejection, stating that when Z is Se, R₆ cannot be an amino acid, peptide, etc., and, thus, R₆ can only be an amino acid, peptide, etc. when Z is O, NH, NR₁ or S. Applicant asserts that the placement of Z and its definition of being only O, NH, NR₁ or S when R₆ is an amino acid, peptide, etc. means that Z cannot be just any atom of the amino acid, peptide, etc. Applicant opines that the same language was used in U.S. Patent No. 6,670,332.

Applicant's traversal has been fully and carefully considered, but fails to be persuasive.

The use of the indefinite article "an" in the phrase "an atom of said amino acid, peptide, polypeptide, protein, mono-, di- or polysaccharide" fails to constitute a specific and particular reference back to the preceding definition of Z to be limited to O, NH, NR₁ or S. The phrase "an atom" is reasonably interpreted to constitute "any atom" of the recited structures of R₆ (i.e., amino acid, peptide, polypeptide, protein, mono-, di- or polysaccharide) in the absence of a specific reference to the particular atoms of Z in question (i.e., O, NH, NR₁ or S), which clearly constitutes a conflicting definition of what Z may comprise. In addition, the fact that the limitation "wherein Z is an atom of said amino acid, peptide, polypeptide, protein, mono-, di- or polysaccharide" is separated from the other pertinent limitations regarding Z and R₆ by a comma is reasonably understood to be a separate and distinct definition of Z in the absence of a clarifying amendment to the claims.

Applicant also cites to U.S. Patent No. 6,670,332 as using this same language. This is unpersuasive. Applicant is reminded that each case before the Office is decided on its own merits.

Art Unit: 1629

Decisions made during the course of prosecution of previous applications are not binding to the course of prosecution of any other application pending before the Patent Office. In addition, the reference to patent claim 2 of the '332 patent as providing a supporting "understanding" of the language by reciting "Z is O and R₆ is an amino acid or peptide linked to Z as an ester" is not persuasive in clarifying the language of the instant claims because (1) such a limitation does not appear in the instant claims and (2) Applicant has failed to clarify the intent of Z in relation to R₆ such that the scope of Z is clearly set forth in the instant claims. As a result, the rejection stands.

For these reasons *supra*, and those previously set forth at p.8-9 of the Office Action dated January 20, 2011, rejection of claims 68 and 85 is proper.

Claims 71, 73-74 and 87 remain rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention, for the reasons set forth at p.9 of the previous Office Action dated January 20, 2011, of which said reasons are herein incorporated by reference.

Response to Applicant's Arguments

Applicant traverses the instant rejection, stating that, when R₇ and R₈ are the same as defined for R₃ and R₄, then R₇ and R₈ can both be the same or different substituents just like R₃ and R₄ and, in addition, only one of R₇ and R₈ also can be an amino acid, peptide, etc. and the nitrogen of the structure is part of that amino acid, peptide, etc. Applicant again states that the same language is found in U.S. Patent No. 6,670,332 and, thus, the language is clear and not indefinite.

Applicant's traversal has been fully and carefully considered, but fails to be persuasive.

The use of the conjunction "and" in the limitation "R₇ and R₈ are independently selected from the group defined for R₃ and R₄ and one of R₇ and R₈ can further be an amino acid, peptide, polypeptide,

Art Unit: 1629

protein or mono-, di- or polysaccharide" complicates the interpretation of the claim because it is unclear if one of R₇ and R₈ is selected from R₃ and R₄ and one of R₇ and R₈ is an amino acid, peptide, etc. or if R₇ and R₈ are each selected from R₃ and R₄ and, alternatively, one of R₇ and R₈ may be an amino acid, peptide, etc. The presence of the conjunction "and" at l.6 of p.4 of the claims conflicts with the phrase "can further be" at l.7 of p.4 of the claims because it is unclear if it is required (i.e., by the use of "and") that one of R₇ and R₈ is an amino acid, peptide, etc. or is it is merely optional that one of R₇ and R₈ is an amino acid, peptide, etc.

Applicant also cites to U.S. Patent No. 6,670,332 as using this same language. This is unpersuasive. Applicant is reminded that each case before the Office is decided on its own merits. Decisions made during the course of prosecution of previous applications are not binding to the course of prosecution of any other application pending before the Patent Office.

For these reasons *supra*, and those previously made of record at p.9 of the Office Action dated January 20, 2011, rejection of claims 71, 73-74 and 87 is proper.

Conclusion

Rejection of claims 68, 71, 73-74 and 85-87 is proper.

No claims of the present application are allowed.

Applicant is requested to specifically point out the support for any amendments made to the disclosure in response to this Office action, including the claims (MPEP §714.02 and §2163.06). Note that support should be provided for amendments to previously pending claims, as well as any newly added claims. In doing so, applicant is requested to refer to pages and line numbers in the as-filed specification, not the published application. Due to the procedure outlined in MPEP §2163.06 for interpreting claims, it is noted that other art may be applicable under 35 U.S.C. §102 or 35 U.S.C. §103(a) once the aforementioned issue(s) is/are addressed.

Art Unit: 1629

Applicant is requested to provide a list of all copending U.S. applications that set forth similar subject matter to the present claims and share an inventor or assignee with the instant application. A copy of such copending claims is requested in response to this Office action in order to assist the examiner with double patenting analysis in the application.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Leslie A. Royds Draper whose telephone number is (571)272-6096. The examiner can normally be reached on Monday-Friday (9:00 AM-5:30 PM).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey S. Lundgren can be reached on (571)-272-5541. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>.

Art Unit: 1629

Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Leslie A. Royds Draper/
Primary Examiner, Art Unit 1629

May 18, 2011